

K082838108c

510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: September 24, 2008

NOV 25 2008

1. Company making the submission:

Company	
Name	Ortholusion Co., Ltd.
Address	#104 Suntechcity B/D 513-15 Sangdaewon-dong, Joongwon-gu, Kyunggi-do, KOREA, REPUBLIC OF 462-120
Phone	+82 31 777-2245
Fax	+82 31 777-2244
Contact	Mr. Choi, Kwang Sun
Internet	orlus@ortholusion.com

2. Device

- Proprietary Name – ORLUS mini screw
- Common Name – Small bone screw
- Classification Name – Endosseous dental implant

3. Predicate Device

- Ortholusion Co., Ltd./ ORLUS Mini Screw/ K050568 and K052968
- Jeil Medical Corporation/ Dual Top Anchor System Screws/ K033767

4. Classifications names & Citations:

21 CFR 872.3640, DZE, Endosseous dental implant, Class2

5. Description:

ORLUS mini screw is intended to provide a fixed anchorage for orthodontic movement of teeth. It is 1.4~1.8mm in diameter and ranges from 5~13mm in total length. It is made of Titanium 6Al-4V alloy. There is a hole in the screw head with which a wire can be hung to fix the maxilla and mandible. It is used temporarily and removed after orthodontic treatment has been completed. It is supplied sterile and intended for single use only.

K082838

6. Indication for use:

The ORLUS Mini Screw is intended for use as temporary anchor for orthodontic treatment.

7. Contra-indications:

- Osteoporosis
- Advanced diabetes
- Metal allergies

8. Review:

ORLUS Mini Screw has the same device characteristics, material, design and intended use as the predicate device.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Ortholusion Co., Ltd. Concludes that ORLUS Mini Screw is safe and effective and substantially equivalent to the predicate device as described herein.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ortholuton Company, Limited
C/O Ms. Cathryn N. Cambria
Arkin Consulting Group, LLC
5536 Trowbridge Drive
Dunwoody, Georgia 30338

NOV 25 2008

Re: K082838

Trade/Device Name: ORLUS Mini Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 5, 2008
Received: November 7, 2008

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

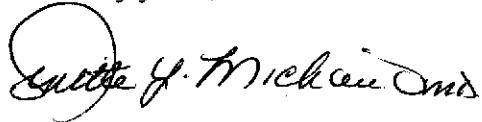
Page 2 – Ms. Cambria

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

181

K082838

Indications for Use Statement

510(k)
Number
(if known)

Device Name ORLUS mini screw

Indications for Use The ORLUS mini screw is intended for use as temporary anchor for orthodontic treatment.

Prescription Use ✓
(Per 21 CFR 801, Subpart D)

OR

Over-The-Counter Use _____
(21CFR801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. E. L. F. M. S.

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082838